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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,574	07/20/2001	Frank A. Skraly	MBX 039	2982

23579 7590 01/27/2003

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/27/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,574

Applicant(s)

SKRALY ET AL.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1,8,11 . 6) ☐ Other: _____

DETAILED ACTION

Claims 1-21 are pending.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 10 is acknowledged.

The traversal is on the ground(s) that the restriction requirement is incomplete. The examiner apologizes the incomplete restriction and the reasons for the restriction requirement is listed below. Examiner notes that the supplemental restriction requirement (Paper No. 12), containing the missing reasoning in the restriction, has been withdrawn at the request of the applicant.

Inventions II and IV are patentably distinct because DNA and a polyhydroxyalkanoate are different compounds, each with its own chemical structure and function, and they have different utilities.

Inventions II and (I and III) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention II can be made synthetically. Also, the product of Invention II can be made by the method of Invention I or III.

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The methods of Inventions I and III are patentably distinct as employing different products. Invention III employs mutant microorganisms while Invention I employs wildtype microorganisms.

The requirement for the election of species is withdrawn.

Claims 11-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hein et al.

Hein et al. (WO 98/39453) teach a method for producing polyhydroxyalkanoates by providing genetically engineered organisms, which express a PHA synthase and a 1,4-butanediol (claims 30-50, pages 39-40, page 3, 2nd paragraph and page 4, 1st paragraph). The genetically modified organisms of Hein et al. naturally express aldH and dhaT genes. Therefore, the teachings of Hein et al. anticipate claims 1, 4 and 8-10.

Claims 1, 5 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al.

Lee et al. teach a method for producing polyhydroxyalkanoates by providing genetically engineered organisms, which express a PHA synthase and a 1,3-butanediol (abstract, page 901 and pages 907-908). The genetically modified organisms of Lee et al. naturally express aldH and dhaT genes. Therefore, the teachings of Lee et al. anticipate claims 1, 5 and 8-10.

Claims 1, 5, 7-8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Skraly et al.

Skraly et al. (U.S. Patent No. 6,329,183) teach a method of method of producing polyhydroxyalkanoates from diols with oxidoreductase, acyl-CoA transferase, acyl-CoA synthetase, B-ketothiolase, acetoacetyl-CoA reductase and PHA synthase (claims 1-13). Therefore, the teaching of Skraly et al. anticipates claims 1, 5, 7-8 and 10.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1, 5, 7-8 and 10 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/944,243 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

Skraly et al. (U.S. Patent Application No. 09/944,243) teach a method of method of producing polyhydroxyalkanoates from diols with oxidoreductase, acyl-CoA transferase, acyl-CoA synthetase, B-ketothiolase, acetoacetyl-CoA reductase and PHA

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synthase (claims 1-17). Therefore, the teaching of Skraly et al. anticipates claims 1, 5, 7-8 and 10.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hein et al. in view of Doi et al.

Hein et al. (WO 98/39453) teach a method of producing polyhydroxyalkanoates, as discussed above.

The difference between the reference of Hein et al. and the instant invention is that the reference of Hein et al. does not teach a method of producing polyhydroxyalkanoates using 1,6-hexanediol or 1,5-pentanediol.

Doi et al. teach that polyhydroxyalkanoates can be produced from 1,6-hexanediol or 1,5-pentanediol (abstract, page 37).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the diols of Doi et al. in the method taught by Hein et al. The motivation of using the diols of Doi et al. is to produce various copolyesters possessing different physical and chemical properties for applications in industry. One of ordinary skill in the art would have had a reasonable expectation of success since the enzymes in the method of Hein et al. are well capable of transforming 1,6-hexanediol or 1,5-pentanediol into polyhydroxyalkanoates.

Claims 1-2 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hein et al. in view of Asrar et al.

Hein et al. (WO 98/39453) teach a method of producing polyhydroxyalkanoates, as discussed above.

The difference between the reference of Hein et al. and the instant invention is that the reference of Hein et al. does not teach a method of producing polyhydroxyalkanoates using 1,2-ethanediol or 1,2-propanediol.

Asrar et al. (WO 99/64617) teach that polyhydroxyalkanoates can be produced from 1,2-ethanediol or 1,2-propanediol (page 7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the diols of Asrar et al. in the method taught by Hein et al. The motivation of using the diols of Asrar et al. is to produce various copolyesters possessing different physical and chemical properties for applications in industry. One of ordinary skill in the art would have had a reasonable expectation of success since the enzymes in the method of Hein et al. are well capable of transforming 1,2-ethanediol or 1,2-propanediol into polyhydroxyalkanoates.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. in view of Doi et al.

Lee et al. teach a method of producing polyhydroxyalkanoates, as discussed above.

The difference between the reference of Lee et al. and the instant invention is that the reference of Lee et al. does not teach a method of producing polyhydroxyalkanoates using 1,6-hexanediol or 1,5-pentanediol.

Doi et al. teach that polyhydroxyalkanoates can be produced from 1,6-hexanediol or 1,5-pentanediol (abstract, page 37).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the diols of Doi et al. in the method taught by Lee et al. The motivation of using the diols of Doi et al. is to produce various copolyesters possessing different physical and chemical properties for applications in industry. One of ordinary skill in the art would have had a reasonable expectation of success since the enzymes in the method of Lee et al. are well capable of transforming 1,6-hexanediol or 1,5-pentanediol into polyhydroxyalkanoates.

Claims 1-2 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. in view of Asrar et al.

Lee et al. teach a method of producing polyhydroxyalkanoates, as discussed above.

The difference between the reference of Hein et al. and the instant invention is that the reference of Hein et al. does not teach a method of producing polyhydroxyalkanoates using 1,2-ethanediol or 1,2-propanediol.

Asrar et al. (WO 99/64617) teach that polyhydroxyalkanoates can be produced from 1,2-ethanediol or 1,2-propanediol (page 7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the diols of Asrar et al. in the method taught by Lee et al. The motivation of using the diols of Asrar et al. is to produce various

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copolyesters possessing different physical and chemical properties for applications in industry. One of ordinary skill in the art would have had a reasonable expectation of success since the enzymes in the method of Lee et al. are well capable of transforming 1,2-ethanediol or 1,2-propanediol into polyhydroxyalkanoates.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 7-8 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,329,183. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: methods of producing polyhydroxyalkanoates from diols with oxidoreductase, acyl-CoA transferase, acyl-CoA synthetase, B-ketothiolase, acetoacetyl-CoA reductase and PHA synthase.

Claims 1, 5, 7-8 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 09/944,243. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: methods of producing polyhydroxyalkanoates from diols with oxidoreductase, acyl-CoA transferase, acyl-CoA synthetase, B-ketothiolase, acetoacetyl-CoA reductase and PHA synthase.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

January 23, 2003


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SUPERVISORY PATENT EXAMINER
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